

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

NATURAL PRODUCTS ASSOCIATION,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Case No. 8:21-cv-03112-TDC

JOINT STATUS REPORT

Pursuant to the Court's August 12, 2022, Marginal Order (ECF No. 33), the parties file this joint status report.

1. On December 6, 2021, Plaintiff Natural Products Association (NPA) filed its Complaint against Defendants for declaratory and injunctive relief in connection with a product called N-acetyl-L-cysteine.

2. Pursuant to the Court's February 7, 2022 Order (ECF No. 17), NPA filed its First Amended Complaint on February 21, 2022 (ECF No. 19).

3. On March 14, 2022, Defendants advised the Court of their intent to move to dismiss the First Amended Complaint for lack of subject matter jurisdiction (ECF No. 24). Defendants also explained that, no later than March 31, 2022, the Food and Drug Administration (FDA) intended to answer a citizen petition that NPA had submitted to FDA, which would address at least the first request in that petition. *Id.*

4. On March 31, 2022, FDA responded to the first request in NPA's citizen petition.

5. To provide NPA time to evaluate FDA's citizen petition response and determine whether to file a second amended complaint, on April 7, 2022, the parties filed a joint motion regarding certain deadlines in this case (ECF No. 26), which the Court granted on April 8, 2022 (ECF No. 27).

6. On April 22, 2022, FDA published notice in the Federal Register of a draft guidance titled, "Policy Regarding N-acetyl-L-cystine: Guidance for Industry." *See* Notice of Availability, 87 Fed. Reg. 24170 (Apr. 22, 2022). The notice instructed the public to submit comments on the draft guidance by May 23, 2022, to ensure that FDA considers the comments before working on the final version of the guidance.

7. To provide NPA time to review FDA's final guidance, once issued, on May 19, 2022, the parties jointly moved this Court to extend certain deadlines in this case (ECF No. 30). The Court granted that motion (ECF No. 31), and ordered the following:

- a. On or before August 10, 2022, NPA will file an unopposed second amended complaint or the parties will file a joint status report.
- b. If NPA files a second amended complaint, Defendants' answer or response will be due within 30 days from the date of service.

8. On August 2, 2022, FDA published notice in the Federal Register of a final guidance titled, "Policy Regarding N-acetyl-L-cystine: Guidance for Industry." *See* 87 Fed. Reg. 47220 (Aug. 2, 2022).

9. On August 10, 2022, the parties submitted a joint status report noting that NPA stated that it needed additional time to review the guidance, and that Defendants did not object to this request. (ECF No. 32). The parties proposed to file a joint status report in 30 days. The Court granted that request. (ECF No. 33).

10. The parties subsequently met and conferred and now jointly propose the following, subject to the Court's approval:

- a. On or before October 14, 2022, NPA will file an unopposed second amended complaint.
- b. Defendants' answer or response will be due on November 18, 2022.

Dated: September 14, 2022

Respectfully submitted,

/s/ Kevin M. Bell

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Motion: Granted 9/15/22

Theodore D. Chuang
United States District Judge